

104TH CONGRESS
1ST SESSION

H. R. 1744

To clarify the scope of coverage and amount of payment under the medicare program of items and services associated with the use in the furnishing of inpatient hospital services of certain medical devices approved for investigational use.

IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 1995

Mr. THOMAS introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To clarify the scope of coverage and amount of payment under the medicare program of items and services associated with the use in the furnishing of inpatient hospital services of certain medical devices approved for investigational use.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Advanced Medical De-
5 vices Access Assurance Act of 1995".

1 **SEC. 2. CLARIFICATION OF MEDICARE COVERAGE OF**
2 **ITEMS AND SERVICES ASSOCIATED WITH**
3 **CERTAIN MEDICAL DEVICES APPROVED FOR**
4 **INVESTIGATIONAL USE.**

5 (a) **COVERAGE.**—Nothing in title XVIII of the Social
6 Security Act may be construed to prohibit coverage under
7 part A or part B of the medicare program of items and
8 services associated with the use of a medical device in the
9 furnishing of inpatient hospital services (as defined for
10 purposes of part A of the medicare program) solely on the
11 grounds that the device is not an approved device, if—

12 (1) the device is an investigational device; and
13 (2) the device is used instead of an approved
14 device.

15 (b) **CLARIFICATION OF PAYMENT AMOUNT.**—Not-
16 withstanding any other provision of title XVIII of the So-
17 cial Security Act, the amount of payment made under the
18 medicare program for any item or service associated with
19 the use of an investigational device in the furnishing of
20 inpatient hospital services (as defined for purposes of part
21 A of the medicare program) may not exceed the amount
22 of the payment which would have been made under the
23 program for the item or service if the item or service were
24 associated with the use of an approved device.

25 **SEC. 3. DEFINITIONS.**

26 In this Act—

1 (1) the term “approved device” means a medi-
2 cal device which has been approved for marketing
3 under pre-market approval under the Federal Food,
4 Drug, and Cosmetic Act or cleared for marketing
5 under a 510(k) notice under such Act; and

6 (2) the term “investigational device” means a
7 medical device (other than a device described in
8 paragraph (1)) which is approved for investigational
9 use under section 520(g) of the Federal Food, Drug,
10 and Cosmetic Act.

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